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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/798,856      | 03/11/2004  | Debra Alida Odink    | R0081D-DIV          | 6670             |

24372 7590 03/21/2005  
ROCHE PALO ALTO LLC  
PATENT LAW DEPT. M/S A2-250  
3431 HILLVIEW AVENUE  
PALO ALTO, CA 94304

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| EXAMINER |
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CHANNAVAJJALA, LAKSHMI SARADA

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| ART UNIT | PAPER NUMBER |
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1615

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |   |                                     |  |
|------------------------------|---|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/798,856        | <b>Applicant(s)</b><br>ODINK ET AL. |  |
|                              | <b>Examiner</b><br>Lakshmi S. Channavajjala | <b>Art Unit</b><br>1615             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3-11-04</u> . | 6) <input type="checkbox"/> Other: ____.  |

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### DETAILED ACTION

Receipt of IDS and preliminary amendment dated 3-11-05 is acknowledged.

Claims 1-25 have been canceled and claims 26-35 are presented for prosecution.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over a combination of US 5,952,362 to Courmoyer et al ('362) and US 5,968,554 to Beiman et al ('554).

'362 teach alkylsulfonamide compounds that read on the instant compounds of formula I (col. 38-42). In particular, '362 teach the specific compound of claims 28 and

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35 (col. 41, lines 10-15). Applicants also admit in the instant specification that the compounds are taught by '362. '362 teach preparing pharmaceutical compositions comprising the sulfonamide compounds in the form of tablets, capsule or other dosage forms by adding the desired excipients, stabilizing, flavoring agents etc (col. 47-48), for oral as well as parenteral application. '362 teach dosage forms for oral administration but fails to teach the claimed nucleus core, a first layer comprising a polymer sealing the core ad a second layer comprising the claimed compounds.

'554 teach sustained release preparations of drug, wherein a core containing an active agent teach phenytoin as an active agent and other pH dependent soluble drugs. '554 teaches a layer of active ingredient of active ingredient that is immediately released in to the gastric juice of the stomach and a second and third layers of active ingredients is protected from gastric juices by an enteric coat placed in between the layers (col. 6). Among the enteric polymers that make up the layer over the coating, '554 teach carboxymethyl cellulose ethylcellulose, Eudragit (col. 7-8) etc, which do not dissolve at acidic pH in the stomach. The method of preparing the composition comprising a core, sprayed with enteric polymer, drying the coated polymer and further coating with additional layers is also described by '554 and thus meet the process steps claimed.

Thus, preparing sustained release dosage forms, which release drugs in the stomach (immediately) as well as a delayed release in the intestine, without exposing drug to acidic pH, is taught by '554. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention in the art to prepare the sulfonamide compositions of '362 in the form of sustained release tablets or capsules by

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coating the core with an enteric polymer and further coating a second layer over the enteric coating a second drug containing layer because '554 teach that the drug layer on the outside of the dosage ensure immediate delivery that allows apportion of drug to pass in to the stomach while allowing a portion of the drug to pass into the duodenum. This allows one to achieve a controlled release of the drug in the intestine and the stomach. Instant claim requires a nucleus but does not state the core is free of drug. Therefore, one of an ordinary skill in the art would have expected to achieve an immediate as well as extended release of the drug from the outermost coating as well as inner layers or nucleus core, as suggested by '554.

### ***Specification***

The use of the trademark Eudragit (L or S series) has been noted in the application. It should be capitalized wherever it appears and be accompanied by the generic terminology:

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615

March 14, 2005